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## The Strange Fixation with Drug Importation: Who *Really* Wins?

*[This is the third in a series of RPC papers regarding the issue of prescription drug importation. The first paper, "Pharmaceutical Price Controls Abroad: An Unfair Trade Policy," released November 6, 2003, highlighted trade policy concerns. The second, "Prescription Drug Importation: First, Do No Harm," released on April 27, 2004, examined health risks. This paper provides an economic analysis of the issue.]*

### Executive Summary

- Economists have expressed skepticism about the potential consumer savings of a nationwide prescription drug importation policy.
- Drug-importation advocates point to anecdotal evidence as the basis for such a policy. While the savings for individuals have been real in some cases, such price differences will disappear once the dynamic shifts from small-scale, direct-to-consumer drug importation to a nationwide importation regime. This is because a nationwide policy of importing price-controlled drugs amounts to a concept called *parallel trade*, a concept that is far different from free trade.
- Recently, Democrat Presidential nominee John Kerry called for wholesalers and distributors to participate in a nationwide drug importation regime. Yet, evidence from the European Union suggests that when these middlemen are involved, they — not consumers — capture most of the price differential.
- A recent London School of Economics study shows that the parallel trade of drugs in Europe has resulted in savings of less than 2 percent by consumers. Similarly, a World Bank study found that parallel trade in Sweden cost consumers about as much as it saved them after accounting for reshipping and repackaging costs, as well as profits to traders.
- Even worse, the European example shows that a national importation policy could *harm consumers*. Since the introduction of parallel trade in the last decade, European drug manufacturers' research and development (R&D) spending has slumped relative to their American competitors', which has meant fewer new medications coming to market.
- Thus, it is evident that the goal of a national drug importation policy — to reduce prices in the United States by allowing international drug wholesalers and distributors to purchase price-controlled drugs in one jurisdiction only to resell them here at a profit — will not be achieved. It is likely to yield consumers little if any measurable savings and may cost them in terms of reduced medical innovation.

## Introduction

In response to constituents' complaints about the higher price of prescription drugs in the United States relative to those in Canada and elsewhere, many in Congress now advocate the importation of prescription drugs. Whether from cross-border purchases or Internet sales, some Americans have turned to Canada and other foreign pharmacies as a way to purchase their prescription drugs at prices lower than they can find in the United States.

With lower prices available in foreign countries, many believe that U.S. consumers would automatically benefit from lower prices if the U.S. government were to adopt a nationwide importation policy. The theory of "free trade" is invoked to support this supposition. Unfortunately, that is not the way it works in practice. The reality is that, once the dynamic shifts from small-scale, direct-to-consumer drug importation to a nationwide importation regime of price-controlled drugs, the potential consumer savings will evaporate as wholesalers and distributors enter the picture.

As the old saying goes: for every complex problem there is a simple — and wrong — solution. This paper will examine how a widescale importation regime differs from today's individual purchases, and how middlemen (who would be the primary purchasers of drugs in foreign markets) would capture most of the potential consumer savings. It also will examine the effect of such a policy on the future development of innovative new medicines.<sup>1</sup>

## Will a Nationwide Drug Importation Policy Yield Consumer Savings?

Members of Congress have cited numerous examples of consumers saving money by purchasing their prescriptions in foreign markets. For instance, Senator Mark Dayton (D-MN) recently described a bus trip of Minnesotans to Canada that resulted in an average savings of \$250 for each participating senior citizen.<sup>2</sup> Senate Minority Leader Tom Daschle (D-SD) spoke of a couple in South Dakota who managed to save \$425 in monthly prescription costs after calling a pharmacy in Canada.<sup>3</sup>

The research often confirms these anecdotes. For example, the Food and Drug Administration (FDA) found a 68-percent difference in the price of a three-month supply of Lipitor (a popular cholesterol-reducing drug) between an on-line Canadian pharmacy and a domestic on-line pharmacy.<sup>4</sup> It is no wonder that Members of Congress feel compelled to respond

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<sup>1</sup> Note: this RPC paper recognizes that the health risks associated with a nationwide importation policy also represent a significant cost. That cost, while extremely important to the debate, will not be addressed here, but is detailed in a previous RPC paper, "Prescription Drug Importation: First, Do No Harm," released on April 27, 2004. Additionally, it must be noted that bureaucratic costs associated with increased FDA oversight responsibilities — in addition to those associated with that agency's role in assuring the efficacy of the drugs — will not be minimal, and so will add to the cost side of the equation. However, since the FDA has not yet addressed the additional budgetary requirements that would be imposed on it by any of the leading drug-importation legislative proposals, these bureaucratic costs also are not addressed in this RPC paper.

<sup>2</sup> Senator Mark Dayton, *Congressional Record*, "Cost of Prescription Drugs," June 2, 2004.

<sup>3</sup> Senator Tom Daschle, *Congressional Record*, "First Day of Medicare Drug Card Enrollment," May 4, 2004.

<sup>4</sup> FDA, "Drug Importation: FDA Exhibits." The agency conducted a price comparison of Lipitor, which discovered 90 tablets (20 mg) to cost \$275.97 from Drugstore.com and \$187.40 from Crossborderpharmacy.com. Exhibit dated, July 30, 2004.

to such price differences by advocating the importation of prescription drugs from countries with price controls.

However, what proponents of such a policy actually are advocating is *not* free trade because the prices of the drugs that would be imported are not set by the market but by the government through price controls. In Canada and Europe, among others, these price controls often are part of broader government-run health systems. This helps explain why, if U.S. law allowed for widespread, national importation of such price-controlled drugs, the dynamics would change significantly.

### **Counterintuitive Effects of Importation**

Currently, drug importation — while illegal, even for individuals — is conducted on a very small scale.<sup>5</sup> On a micro level, it is easy to understand why an American consumer who travels across the border to Canada, or uses a foreign pharmacy's web site, could save significant sums on prescription drugs. By accessing foreign price-capped drugs directly, consumers effectively are treated as if they were residents, enjoying the lower prices mandated by those governments. If the U.S. government were to implement a national drug importation policy, international wholesalers and distributors and domestic pharmacies would begin to compete directly with American consumers for the fixed supply of price-controlled drugs in foreign markets.

For instance, under a national drug importation scheme, a pharmacy in Macon, Georgia could hypothetically import drugs from Greece where the prices are much lower. However, the actual price that the Georgia pharmacy would pay could be much higher because a wholesaler would be involved in the initial purchase and reshipment of such drugs. Although the wholesaler could purchase the drugs in Greece at a price capped by the Greek government, it still would incur significant additional expenses (administrative, repackaging, and reshipping) before the drugs could be sold in the American market. In addition to passing along these expenses to the Georgia pharmacy, the wholesaler also would seek to capture as much of the margin between the Greek price (plus its expenses) and the American price as possible. The same would be true of the Georgia pharmacy, which would be inclined to improve its own profit margins rather than pass along any savings (to the extent they materialize) to consumers.

### **Economists Agree: Price Savings to Consumers Evaporate**

Several economists who have studied the dynamics of a wide-scale drug importation policy are skeptical that consumers would save money if it were implemented broadly. For instance, Robert D. Reischauer, president of the Urban Institute and a former director of the Congressional Budget Office (CBO), recently assessed that a wide-scale policy would fail to create a “sea change” regarding the price of pharmaceuticals for U.S. consumers and would be more of a “feel-good” than a helpful action; Joseph Antos, a health policy analyst at the American Enterprise Institute, echoed this assessment, explaining, “Most of the savings would not necessarily be passed on to the consumer.”<sup>6</sup>

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<sup>5</sup> According to a *Congressional Quarterly Weekly* article, “Weighing Promise and Perils of Drug Importation,” IMS Consulting “estimates that 4 to 7 percent of prescription drug users have tried importation in person or through mail.” July 24, 2004, Volume 62, No. 30, pg. 1789.

<sup>6</sup> Both experts' statements are included contained in the *Congressional Quarterly Weekly* article, “Weighing Promise and Perils of Drug Importation,” July 24, 2004, Volume 62, No. 30, pg. 1791.

Rather, both economists agree that the wholesalers and distributors are among those who would step in and extract most of the savings that might be realized from drug importation. These assessments underscore that the ad hoc savings seen by a small number of individuals who today cross the border into Canada, or buy on-line from a foreign pharmacy, simply will not exist in a market where millions of consumers are competing for the best price against wholesalers for a fixed supply of foreign price-controlled drugs.

## The ‘Free Trade’ Theory

As noted above, an oft-repeated argument for prescription drug importation is that it would apply the principles of “free trade” to pharmaceutical markets to produce the same consumer benefits and efficiency gains associated with unimpeded trade in other goods and services.<sup>7</sup>

Those who hold a “free-trade-for-prescription-drugs” view explain price differentials between nations as perversions caused by the existing ban on the importation of patented drugs into the United States by anyone other than the drug’s manufacturer.<sup>8</sup> The reality is that prices for nearly all products differ among nations. This is due to the volatility of exchange rates, as well as country-specific factors such as relative income, price sensitivity, distribution costs, and tax and regulatory policies.<sup>9</sup> Such factors, for example, caused the average price of an automobile to be 16 percent higher in the United States than in Canada in 1999.<sup>10</sup>

In the market for prescription drugs, these macroeconomic differences are further exacerbated by price controls, which most developed countries (except the United States) explicitly impose.<sup>11</sup> As the European Commission makes clear, “Without exception, there is no Member State without direct or indirect price controls for pharmaceuticals.”<sup>12</sup> The same is true of Canada, where the Patented Medicine Prices Review Board determines unilaterally the price of each prescription drug sold in the country.<sup>13</sup> These price-control systems are not representative of free trade — they are its antithesis. As a consequence, the average price for patented drugs in other industrialized countries is 35 percent to 55 percent lower than in the United States.<sup>14</sup>

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<sup>7</sup> Senator Byron Dorgan, *Congressional Record*, S8209, June 19, 2003.

<sup>8</sup> The Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits anyone other than the U.S. manufacturer of a prescription drug from importing that drug into the United States § 381(d)(1). The Secretary, however, is authorized to allow the importation of any drugs that are required for emergency medical care and the FDA currently does not enforce this prohibition against individuals who import a limited supply of prescription drugs for personal use.

<sup>9</sup> John Kay, “Rip-off Britain,” *Financial Times*, February 16, 2000.

<sup>10</sup> John R. Graham, “Prescription Drug Prices in Canada and the United States,” *The Frazier Institute*, Public Policy Sources, No. 70, September 2003.

<sup>11</sup> For an overview of other price control examples, see U.S. Senate Republican Policy Committee, “Pharmaceutical Price Controls Abroad: An Unfair Trade Policy,” November 6, 2003.

<sup>12</sup> European Commission, “Parallel Trade of Pharmaceuticals,” available at: <http://www.eaepc.org/parallel.htm>. The European Commission is the supra-governmental body charged with many regulatory responsibilities for the entire European Union.

<sup>13</sup> Graham.

<sup>14</sup> Congressional Budget Office (CBO), “Would Prescription Drug Importation Reduce U.S. Drug Spending,” April 29, 2004.

## **Free Trade Versus Parallel Trade**

Thus, given the absence of a free market for prescription drug sales and pricing in most of the world, it is misleading to suggest that prescription drug importation would be consistent with the principles of free trade. In fact, what proponents of prescription drug importation actually are advocating is the concept known as *parallel trade*,<sup>15</sup> whereby international wholesalers and intermediaries bid away price differences between nations through international arbitrage: buying price-controlled drugs in one jurisdiction to resell them in another at a profit.

Under parallel trade, middlemen exploit price differences between nations. It is important to note that all three major drug importation proposals currently considered in Congress open the door to parallel trading.<sup>16</sup> In fact, a drug importation bill sponsored by Senator Byron Dorgan (D-ND), goes as far as to make it unlawful for a drug company to “deny supplies of prescription drugs to a registered exporter or other person that exports prescription drugs to the United States,” and provides intermediaries with several other significant legal advantages.<sup>17</sup> Democrat Presidential nominee John Kerry said such a plan would “allow individuals, pharmacists, wholesalers, and distributors to reimport FDA-approved prescription drugs from other countries at lower prices.”<sup>18</sup> Each measure, as footnoted below, permits personal and commercial importation and specifically authorizes the importation of pharmaceuticals not just from Canada, but also from Germany, Greece, Portugal, Spain, France, and many other countries that are part of the European Union (EU).

## **Can the “Middleman Problem” Be Eliminated?**

It is important to recognize that these legislative proposals rely on the self-interested decisions of private intermediaries (i.e., wholesalers, distributors, and pharmacies) to reduce drug prices in the United States. However, if the price differential between the low-priced-drug exporting nation and higher-price importer is not large enough to compensate the intermediary for the shipping, repackaging, and administrative expenses, as well as provide for a worthwhile profit opportunity, drug importation legislation will accomplish nothing because the intermediary will not make the trade. Moreover, as explained above, even if the price differential is large enough for the trade to occur, the actual consumer savings would be much less than the published drug-price differential between the two countries.

Confronted with this problem, proponents might then suggest that the answer is to simply eliminate the middleman, i.e., make the government responsible for the acquisition and importation of drugs. Government actions are not motivated by the potential for profits, they might argue, and so it would be able to pass all of the savings to consumers. Yet, if a government

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<sup>15</sup> CBO defines “parallel trade” as “the legal movement of products across borders without the explicit consent of the manufacturer, usually in response to price disparities.”

<sup>16</sup> See: S. 2493, “The Safe Importation of Medical Products and Other Rx Therapies Act of 2004,” introduced by Senator Judd Gregg on June 2, 2004. Similar measures include S. 2328, “The Pharmaceutical Market Access and Drug Safety Act of 2004,” introduced by Senator Byron Dorgan on April 21, 2004, and S. 2307, “The Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004,” introduced by Senator Chuck Grassley on April 8, 2004. In some cases, the authorization extends beyond the European Union, depending upon the discretion of the Secretary for the U.S. Department of Health and Human Services.

<sup>17</sup> S. 2328, Section 27, “Restraint of Trade Regarding Prescription Drugs.”

<sup>18</sup> “Kerry Urges Steps to Curtail Rising Prescription Drug Costs,” Daily Report for Executives, BNA, Inc., August 12, 2004.

agency were created for this purpose, taxpayers would be required to pay for the cost of shipping, repackaging, and administrative expenses, as well as to make up the difference on trades where the acquisition costs exceed the price pharmacies are willing to pay for the drugs.

Although Congress could elect to authorize and appropriate the funds necessary to create such an agency, it must be recognized that this would not be free trade but the government procurement of price-controlled drugs. At this point, it would probably be less costly to simply institute price caps on prescription drugs rather than incur the administrative expenses of such a scheme. However, as economists widely recognize, price caps on prescription drugs hold their own peril for medical innovation, which will be discussed later in the paper.<sup>19</sup>

### **Cost versus Price in Parallel Trade**

The economic effects of real free trade are far different from those associated with parallel trade. Free trade enhances overall economic efficiency and welfare by allowing consumers to purchase lower-cost goods produced in other nations. In this way, the exporting business' greater efficiency or lower-cost production methods provide competition to domestic producers in the form of lower prices.<sup>20</sup> This competition also provides consumers with additional goods that might not otherwise be available, and ultimately reduces the cost of such goods, easing the burden on family budgets. In addition, the importing country benefits from the competition because its labor and capital resources are available for more productive endeavors in which it enjoys a comparative advantage.<sup>21</sup>

By contrast, parallel trade in pharmaceuticals provides none of these economic efficiency gains. This is because lower prices are achieved through explicit price caps, *not more productive or lower-cost production methods*.<sup>22</sup> Specifically, the CBO explains, "Drugmakers can already take advantage of any lower-cost foreign manufacturing environments, so increased parallel trade introduces no new prospect of savings in production."<sup>23</sup>

Parallel trade *leaves the cost of producing pharmaceutical innovations unchanged*, while enriching intermediaries in countries with the most stringent and lowest regulated prices: that is, *it allows the intermediaries — not consumers — to profit* from the exploitation of international price differentials.

## **The Economics of Pharmaceutical Innovation and Production**

It is important to recognize that, by shifting the financial rewards of international trade in pharmaceuticals from research-based drug firms to wholesalers and intermediaries, parallel trade would undermine the incentives to allocate scarce capital toward high-risk drug development.

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<sup>19</sup> John Vernon, "Examining the Link Between Price Regulation, Reimportation, and Pharmaceutical R&D Investment," AEI-Brookings Joint Center, April 2004. The AEI study found that pharmaceutical price caps in the United States would "lead to a decline in industry R&D by between 23.4 and 32.7 percent."

<sup>20</sup> Jennifer Gamber, McGraw Hill's Economics Web Newsletter, October 6, 2003.

<sup>21</sup> A good example of this dynamic is the U.S. transition from traditional manufacturing towards such industries as high technology, research, and advanced services. Steven Landefeld and Barbara M. Fraumeni, "Measuring the New Economy," *Survey of Current Business*, Bureau of Economic Analysis, March 2001.

<sup>22</sup> Patricia M. Danzon, "The Economics of Parallel Trade," *Pharmacoeconomics*, March 1998.

<sup>23</sup> CBO.

Intermediaries capitalizing on low-risk, high-margin arbitrage opportunities would capture the revenues that currently fund new drug development.

This would be a troubling scenario because innovative pharmaceutical products are dependent upon a large amount of research and development (R&D) spending. These R&D efforts also are subject to great scientific uncertainty.<sup>24</sup> Few of the compounds and biologics that companies investigate ever receive FDA marketing approval. And the full cost of those drugs that do receive approval depends significantly on the length in time between the initial investment in research and clinical trials and, the eventual sales of the drug.<sup>25</sup> As a result, the revenue necessary to attract discretionary risk capital for drug development is enormous. Two recent studies of differing methodology estimate the average cost to develop a new drug at \$801 million and \$1.7 billion, respectively.<sup>26</sup> Pharmaceutical R&D budgets consume approximately 21 percent of sales, compared to an economy-wide average of 4 percent.<sup>27</sup>

### **Patents Critical to Assuring Investment in R&D**

The role of patents is critical to the pharmaceutical development process. Public policy is designed to help drug developers recoup these enormous costs through pharmaceutical patents, which give innovators the exclusive right “to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.”<sup>28</sup> In this way, pharmaceutical patents induce investment in R&D by rewarding drug developers with the ability to set prices higher than those that would exist if a competitor were able to immediately reproduce and market a new compound.<sup>29</sup> In the absence of patent protection, research-based pharmaceutical firms simply would not attract (or retain) capital sufficient to fund their R&D budgets.

Indeed, patents — in all sectors of our economy — provide innovators with a temporary “monopoly” over the sale and distribution of their inventions. Yet, if public policy were to prevent the creators from pursuing pricing strategies to generate revenues sufficient to recoup their investment and compensate investors for risk-taking, a patent’s economic value would be greatly undermined and the incentive to invest and invent would be greatly diminished. Patents typically grant patent holders the ability to segment markets and price-discriminate between them because,

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<sup>24</sup> CBO. And John E. Calfee, American Enterprise Institute, in testimony before the Senate Committee on Finance, April 27, 2004.

<sup>25</sup> Henry Grabowski, John Vernon, and Joseph DiMasi, “Returns on R&D for 1990s New Drug Introductions,” March 2002. Available online at: [http://www.dklevine.com/archive/grabow-randd\\_returns.pdf](http://www.dklevine.com/archive/grabow-randd_returns.pdf). A dollar invested in R&D today is worth more than a dollar to be received from drug sales in the future because the dollar today can be invested to earn interest to yield more than a dollar in the future. The Time Value of Money mathematics quantify the value of a dollar through time and are used by investors to determine the amount of future drug sales revenue necessary to recoup today’s R&D investment.

<sup>26</sup> The Tufts Center for the Study of Drug Development, November 30, 2001. And James Gilbert, Preston Henske and Ashish Singh, “Rebuilding Big Pharma’s Business Model,” November 1, 2003.

<sup>27</sup> Danzon.

<sup>28</sup> Wendy H. Schacht and John R. Thomas, “Patent Law and Its Application to the Pharmaceutical Industry,” *Congressional Research Service*, RL30756, September 30, 2002. Pharmaceutical patent law is governed by the provisions outlined in the “Drug Price Competition and Patent Term Restoration Act of 1984” (P.L. 98-147) and the amendments made to it by Title XI of the “Medicare Prescription Drug and Modernization Act of 2003” (P.L. 108-173). NOTE: S. 2328 would eliminate the ability of drug companies to block the importation of patented drugs first sold to overseas wholesalers or pharmacies.

<sup>29</sup> John R. Thomas, “Patents and Drug Importation,” *Congressional Research Service Report for Congress*, RL32400, May 25, 2004.



as mentioned above, patents grant holders the ability to exclude others from importing their patented product.<sup>30</sup> To force an innovator to compete with international intermediaries and wholesalers reselling *its own products* would deprive a patent holder of this important right.

### **The European Lesson: Parallel Trade Devastates R&D Investment**

The introduction of a secondary market in patented drugs through parallel trade would compromise innovators' ability to segment their markets and reduce their sales revenue. And the less revenue generated by pharmaceutical sales, the less risk capital the research-based pharmaceutical firm is able to attract (or retain) to devote to R&D. For proof of this dynamic, one need only consider developments in the EU since parallel trade was introduced in the mid-1990s. Although price controls on pharmaceuticals have existed in Europe at least since 1957,<sup>31</sup> the recent declines in prices charged across the EU can be traced to the mid-1990s when enforcement of the Treaty of Rome allowed parallel imports from traditionally low-priced countries, such as Spain, Portugal, and Greece to begin circulating freely in the European market.<sup>32</sup>

As a result, purchasers in other member states (particularly governments) began to acquire drugs from parallel importers in low-priced nations. By 1998, parallel trade flows were estimated at just under 10 percent of total pharmaceutical sales in Europe, but as much as 25 percent of patented pharmaceutical sales in high-price countries.<sup>33</sup> Governments of high-price member states, including France and Germany, have responded by further imposing stricter price controls.<sup>34</sup>

This trend has devastated the European pharmaceutical industry over the past decade. In 1990, European pharmaceutical firms outspent their U.S. counterparts on R&D, \$9.9 billion compared to \$6.2 billion, but by 2000, U.S. pharmaceutical research firms outspent their EU counterparts, \$29.9 billion to \$21.1 billion.<sup>35</sup> Not surprisingly, this swing in R&D has led to a corresponding change in the location for new drug development: In 1988, Americans developed only 19 of the 50 best-selling drugs worldwide, but by 2003, American firms developed 15 of the top 20 best-selling drugs worldwide and 14 of the top 15 biotechnology drugs.<sup>36</sup> Furthermore, European-headquartered pharmaceutical companies have shifted their own research to the United States due to their inability to generate sufficient revenues in their home markets. This year, only 59 percent of European-headquartered pharmaceutical firms' R&D is conducted throughout Europe, compared to more than 73 percent a decade ago.<sup>37</sup>

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<sup>30</sup> In *Jazz Photo Corp v. United States International Trade Commission* (264 F.3d 1094 (Fed. Cir. 2001), the Court of Appeals for the Federal Circuit ruled that a patent holder can enjoin unlicensed importation from international parallel traders who purchased the patent product on terms different from those prevailing in the U.S. market.

<sup>31</sup> W. Duncan Reekie, "Drug Price Controls: Regulation Without a Cause," International Intellectual Property Institute, available at: [http://www.iipi.org/activities/forums/IP&Public\\_Health/papers/reekie%20paper.pdf](http://www.iipi.org/activities/forums/IP&Public_Health/papers/reekie%20paper.pdf).

<sup>32</sup> Danzon.

<sup>33</sup> Danzon.

<sup>34</sup> Geoff Dyer, "The Wrong Diagnosis: National Champions May Not Cure the ills of the European Drug Industry," *Financial Times*, May 5, 2004.

<sup>35</sup> Calfee. The original figures were in euros, which were converted to dollars based on a 1.24453 euro to \$1 exchange rate.

<sup>36</sup> Dr. David Gratzner, "Price Controls Stifle Drug Development," *Chicago Sun-Times*, September 14, 2003. And Calfee.

<sup>37</sup> Geoff Dyer, "The Wrong Diagnosis: National Champions May Not Cure the ills of the European Drug Industry," *Financial Times*, May 5, 2004.



Aware of this disturbing trend, the European Commission twice has urged the governments of its member states to “agree to refrain from setting maximum prices” for prescription drugs and to replace “the unilateral price-fixing mechanism by a contractual policy.”<sup>38</sup> Bound by the Treaty of Rome to allow for parallel trade, but painfully aware of its consequences, the European Commission is left to beg its member states to eschew the very price caps some U.S. policymakers wish to import.

### **Parallel Trade Has Provided Few Benefits to European Consumers**

Parallel trade has compromised European research-based pharmaceutical firms’ revenues, R&D budgets, and international competitiveness — yet, the expected offsetting consumer benefits have been conspicuously absent. A recent London School of Economics study demonstrates that most of the financial benefits from parallel trade have been captured by parallel importers instead of consumers: the \$8.1 billion of parallel drug sales surveyed produced consumer savings of only \$149 million.<sup>39</sup> That amounts to *a mere 1.8 percent* of the benefit going into consumer pockets. Worse, patients in the low-priced countries have experienced some shortages, as parallel traders redirected drugs intended for their use as a way to capture greater profits in more expensive markets.<sup>40</sup>

In the few instances where parallel trade proves effective at reducing prices, the consumer benefit is more than offset by the resources lost to the parallel trade itself. For example, a World Bank study found that although parallel trade from Spain and Italy reduced pharmaceutical prices in Sweden by between \$19.5 million and \$25.8 million in the late 1990s, such trade wasted \$24 million in real resources.<sup>41</sup> That means that revenues that otherwise would have gone to provide a return to investors willing to provide capital for drug development instead went to reshipping and repackaging costs, as well as the profits of parallel traders, who enjoyed margins of 21 percent.<sup>42</sup>

If the U.S. government adopted a similar approach, wholesalers and distributors would be subjected to the same administrative, repackaging, and transportation costs, as well as varying registration fees to help cover the enormous safety inspection requirements imposed by the FDA and the U.S. Bureau of Customs and Border Protection.<sup>43</sup> Clearly, these added expenses would curtail much of the consumer savings that advocates hope to achieve.

Aware of these dynamics, the CBO estimates that parallel importation of pharmaceuticals would “reduce total drug spending by \$40 billion over 10 years, or by about 1 percent” in the

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<sup>38</sup> European Commission: “Communication on the Single Market in Pharmaceuticals,” November 1998, and the “2003 Communication on a Stronger Pharmaceutical Industry for the Benefit of the Patient.” Available at: <http://europa.eu.int/scadplus/leg/en/lvb/l21227.htm>.

<sup>39</sup> Panos Kavanos, et al. “The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States,” The London School of Economics and Political Science, Special Research Paper, January 2004.

<sup>40</sup> Doug Bandow, “The Free Market Mirage of Reimportation,” Policy Report 180, *Institute for Policy Innovation*, May 2004.

<sup>41</sup> Keith E. Maskus and Mattias Ganslandt, “Parallel Imports of Pharmaceutical Products in the European Union,” *The World Bank*, Working Paper 2630, July 1, 1999. The original figures were in Swedish Krona (SEK), which were converted to dollars based on a 0.13 SEK to \$1 exchange rate.

<sup>42</sup> Maskus and Ganslandt.

<sup>43</sup> See footnote number 12, listing the three leading legislative proposals. Each assesses user fees of differing amounts on intermediaries.

United States.<sup>44</sup> These savings are modest when compared to total U.S. drug spending, which is estimated to be approximately \$4 trillion over 10 years.

### **Trade Negotiations: Opportunities for Future Global Benefit**

As the European Union experiences the ill-effects of parallel trade, the U.S. Trade Representative currently is working to ensure a fairer and more global balance of innovative drug research. For instance, through trade negotiations, the United States and its trading partners can work together to enhance the number of innovative drugs entering the market.<sup>45</sup> One example of this effort is the recently enacted United States-Australia Free Trade Agreement, which commits Australia to improve its pharmaceutical benefits program by adding new appeal mechanisms, creating a “Medicines Working Group,” and providing objective reviews of drugs entering the market. Because Australia maintains a government-approved list of pharmaceutical products, these commitments are an important step toward ensuring both countries benefit from potential medical research.

## **Conclusion**

The anecdotes of significant savings from drug importation seem appealing. Yet, however counterintuitive it may seem to the consumers who have crossed into Canada to make their drug purchases, the economic reality is that such savings would largely evaporate if the United States were to adopt a nationwide importation policy. Parallel trade — as distinct from free trade — provides little savings to consumers. If the U.S. government implicitly caps drug prices through parallel trade (by imposing a nationwide drug importation policy) — with the goal of achieving lower prices for Americans — advocates are bound to be disappointed in the results. Instead of assuming the result will be reduced prices for consumers, drug importation advocates must learn from Europe — not only to steer consumers away from the false hope of savings but also to avoid subjecting them to the effects of less medical research and fewer innovative drug therapies that will be needed in the future.

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<sup>44</sup> CBO.

<sup>45</sup> For further trade negotiation efforts, see footnote #11.